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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,868	11/21/2003	Chengrong Wang	DCS-9082	3058

34500 7590 09/15/2005

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LEGAL DEPARTMENT
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EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,868

Applicant(s)

WANG ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/9/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

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1) Although specific claims may be discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

2) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3) Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for competitive receptor binding assays for certain macrophilin-binding pharmaceutical compounds using the competitor compounds of claims 1 and 3 does not reasonably provide enablement for the analogous use of all of the compounds of claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

For claim 12, it is unclear how the competitive assay method would work for the cases in which the compounds of claim 6 are very closely related structurally to the compounds to be assayed, for example, the claim 6 case in which a compound wherein R, R' = methyl is used to assay FK 506 {wherein the corresponding R, R' definitions are H}. There is inadequate enablement in the specification for determining exactly which structural combinations of "pharmaceutical" and "binding competitor" would be operable for a given "receptor that binds to the pharmaceutical but not significantly to the binding competitor".

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5) Claims 2, 4 and 6-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) For claim 6, the following definitions of "R'" render the claim indefinite since the exact structure of the C24 substituents cannot be determined: "carbonyl", "carboxylate", "amide", "ester", "phosphonate", "phosphate", "sulfonate", "sulfate", "amidine" and "carbamate". The terms in question define types of functional groups but not specific structures. For example, for the term "R'" = "carbonyl" [-C(O)], the terminal substituent at the C24 position would be a "-OC(O)-" group which is non-terminal. "R'" defined as "carboxylate" [C24 substituent = "-OC(O)O⁻"] is similarly incompletely defined as is "carbamate" [C24 substituent = "-OC(O)NH-"].

b) For the same reasons discussed in paragraph **a)** above, claims 2 and 4 are indefinite for the reason that the exact structures of the compounds cannot be determined since the "R" and "R'" definitions contain incomplete structures. It is also unclear how/where the "functional group" is attached to the remainder of the "compound".

c) For claim 6, it is unclear what is meant by the term "effective amount" since the intended use of the compound in the "reagent" is unspecified. The claim is readable on the "compound" *per se* (a "reagent" comprising the "compound" as a single ingredient).

d) For clarification of exactly what is intended, in claim 6 the term "a compound having the formula" should be inserted after the term "effective amount".

e) The use of the terms "pharmaceutical composition" and "pharmaceutical" in claim 7 renders the claim indefinite since it is unclear whether or not these terms are meant to be interchangeable. See also, claims 9 and 12.

f) The term "pharmaceutical composition" of claim 7 implies that other components, in addition to the "pharmaceutical" are present; however, exactly what components are intended is unclear. See also, claims 9 and 12.

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g) In claim 7, the language should be clarified to indicate that the "receptor-pharmaceutical composition" ("receptor-pharmaceutical"?) is a binding complex comprised of the two components. See also, claims 9 and 12.

h) Claim 7 is incomplete in not reciting the steps which effect **i)** the "detecting" of the binding complex and **ii)** the correlating of the "detection" with the "amount of the pharmaceutical". See also, claims 9 and 12.

6) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8) Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by each of FUJISAWA (WO 92/00313) and Kobayashi et al (US 6,338,946).

Each of the references describes anticipating FK 506 compounds which correspond to the structures of instant claims 1-6 wherein the hydroxy groups at the C24 and C32 positions are protected with a carbamate group, as claimed.

See FUJISAWA: formula (I) wherein R¹ is "acyl" and R² is "acyloxy"; page 9, "acyl" defined as "protected carboxy(lower)alkylcarbamoyl", "lower carbamoyl" and "carboxy(lower)alkylcarbamoyl"; for

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claim 6 wherein R' is "ester" and R is "carbonyl", see FUJISAWA wherein R² is "acyloxy" and R¹ is "acyl".

Giving no weight to an intended method of use in a product claim, the "assay reagent" of claim 6 comprising "an effective amount" of the compound appears to be the same as the "pharmaceutical composition" of claim 3 of the reference which contains the same active ingredient.

See Kobayashi et al: formula (I) wherein R¹, R² are "protected hydroxy" wherein the "protective groups" are defined at col. 3, line 64 – col. 4, line 2. For the "assay reagent" of claim 6, see Example 4.

9) Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by FUJISAWA (WO 91/17754).

For anticipatory compounds see FUJISAWA, formula I wherein R¹, R² are protected hydroxy wherein the acyl group is defined at page 6, line 22 – page 7, line 13, e.g. "lower alkylcarbamoyl" optionally substituted with "protected carboxy" (see claim 2 of this application"). Giving no weight to an intended method of use in a product claim, the "assay reagent" of claim 6 comprising "an effective amount" of the compound appears to be the same as the "pharmaceutical composition" of page 9 of the reference which contains the same active ingredient.

10) Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by each of FUJISAWA (WO 91/02736) and Grassberger et al (US 5,665,727).

Each of the references describes compounds which anticipate the compounds of claim 6. See FUJISAWA, formula (I) wherein R⁶ is R⁸COO- and R¹ is R⁷COO- (corresponds to R and R' of claim 6 defined as "carboxylate"); Grassberger et al, formula (I) wherein R¹, R² are "protected hydroxy" the compounds of col. 6, lines 19-55. Giving no weight to an intended method of use in a product claim, the "assay reagent" of claim 6 comprising "an effective amount" of the compound appears to be the same as the pharmaceutical compositions of the reference which contains the same active ingredient.

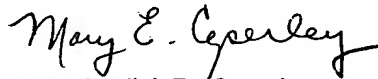
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11) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 13, 2005


Mary (Molly) E. Ceperley
Primary Examiner
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